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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 08/454,529 | 05/30/1995 | JAMES J. HOGAN | 212/083 | 7594 |

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EXAMINER

MARSCHER, ARDIN H

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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/454,529

Applicant(s)

HOGAN ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2004 and 09 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 486-560 and 563-630 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 490, 491 and 593-630 is/are allowed.
- 6) ☒ Claim(s) 486-489, 508, 509, 512, 513, 528 and 529 is/are rejected.
- 7) ☒ Claim(s) 492-507, 510, 511, 514-527, 530-560, & 563-592 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 6/9/04 and 11/9/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 486, 487, 512, 513, 528, and 529 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER has been entered into the claims via the amending to providing embodiments directed to bases 1255-1290 of 16S rRNA (*E. coli* numbering) which limits the target to *Mycoplasma pneumoniae* and the non-target to at least including a *Mycoplasma* specie other than *Mycoplasma pneumoniae* as in the last 4 lines of part a), for example, of instant claim 486. Written support for this amendment was pointed to on pages 55, lines 11-17, and 57, lines 28-32. These specification citations disclose *Mycoplasma pneumoniae* target regions but do not disclose any limitation regarding non-targets which are species of *Mycoplasma* per se other than *Mycoplasma pneumoniae*. It is noted that Table 26 on page 57 of the instant specification compares non-targets which are a "PHYLOGENETIC CROSS SECTION OF BACTERIA" and not

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a comparison to said NEW MATTER non-target subdivision, for example. That is, this subdivision of non-targets to species of *Mycoplasma* per se other than *Mycoplasma pneumoniae* has neither been found as filed in applicants' pointed to sections nor elsewhere in the entire instant disclosure as filed and therefore supports this NEW MATTER rejection. This rejection is necessitated by amendment and applied to independent claims which contain this limitation as well as dependent claims which contain this NEW MATTER via their dependence.

A related NEW MATTER issue is that instant claims 486 and 487 cite base range 65-108 in the "provided" limitation near the end of parts a) therein regarding 16S rRNA whereas in contrast the 16S rRNA range previously filed was directed to bases 60-105. The 65-108 base range was previously cited regarding 5S rRNA only. This rejection is necessitated by amendment.

Applicants are reminded that removal of the above NEW MATTER may raise the new issue of reapplying a prior art rejection based on Stanbridge et al. (P/N 5,851,767) against at least some of the above listed instant claims.

VAGUENESS AND INDEFINITENESS

Claims 508, 509, 512, 513, 528, and 529 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amending in claims 490 and 491, for example, to limit target region correspondence to bases 975-1060 at the end of their respective parts a) of 16 S rRNA causes claims 508 and 509 to be vague and indefinite as to what correspondence is

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meant via citing overlapping but not the same base ranges. This unclarity similarly is present regarding claims 512 and 513 when compared to claim 486, for example, regarding differing but overlapping ranges. Additionally, claims 528 and 529 cite 16S rRNA base range which overlap but are not the same as the corresponding 16S rRNA range limited at the ends of parts a) of claims 486 and 487. Clarification via clearer claim wording is requested. This rejection is necessitated by amendment.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 488, 489, 508, 509, 512, and 513 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Stanbridge et al. (P/N 5,851,767).

This rejection is reiterated and maintained from the previous office action, mailed 12/17/03, regarding claims containing the 16S rRNA region in the 1273-1288 base section as set forth in said previous office action in a *Mycoplasma* hybridization target which falls within the 1255-1290 region of the instant claims. It is noted that claim 488 has not been amended regarding *Mycoplasma pneumoniae* non-targets as has instant claim 486, for example. An inadvertent omission of claim 508 in this rejection previously is hereby corrected as being a typographical error.

CLAIM OBJECTIONS

Claims 492-507, 510, 511, 514-527, 530-560, and 563-592 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 490, 491, and 593-630 are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Since the fee set forth in 37 CFR 1.17(r) for a first submission subsequent to a final rejection has been previously paid, applicant, under 37 CFR 1.129(a), is entitled to have a second submission entered and considered on the merits if, prior to abandonment, the second submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a second submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and the appeal fee set forth in 37 CFR 41.20(b) were filed prior to or with the payment of the fee

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set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 26, 2005


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER